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## NOTICE OF ALLOWANCE AND FEE(S) DUE

27879

7590

02/05/2009

INDIANAPOLIS OFFICE 27879 BRINKS HOFER GILSON & LIONE ONE INDIANA SQUARE, SUITE 1600 INDIANAPOLIS, IN 46204-2033 EXAMINER

BOUCHELLE, LAURA A

ART UNIT PAPER NUMBER

3763 DATE MAILED: 02/05/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813.806	03/31/2004	Constantin Cope	8627/487 (PA-5391RFB)	7536

TITLE OF INVENTION: BLOODLESS PERCUTANEOUS INSERTION SYSTEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	05/05/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where ar in m

appropriate. All further indicated unless correct maintenance fee notifica	correspondence including debelow or directed of titions.	ng the Patent, advance onerwise in Block 1, by (	orders and notification of a) specifying a new corr	maintenance fees vespondence address	vill be ; and/or	mailed to the current (b) indicating a separ	correspondence address as rate "FEE ADDRESS" for	
CURRENT CORRESPOND	Fe pa	Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, mus have its own certificate of mailing or transmission.						
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INDIANAPOLI	S, IN 46204-2033		Г				(Depositor's name)	
							(Signature)	
							(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	R	ATTO	RNEY DOCKET NO.	CONFIRMATION NO.	
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nonprovisional	NO	\$1510	\$300	\$0		\$1810	05/05/2009	
EXAM	IINER	ART UNIT	CLASS-SUBCLASS					
BOUCHELL	E, LAURA A	3763	604-167010					
"Fee Address" ind PTO/SB/47; Rev 03-0	oondence address (or Cha B/122) attached. lication (or "Fee Address D2 or more recent) attach	2. For printing on the patent front page, list  (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is 3						
Number is required.	·		listed, no name will b	e printed.				
PLEASE NOTE: Un	less an assignee is ident th in 37 CFR 3.11. Comp	ified below, no assignee	THE PATENT (print or t data will appear on the T a substitute for filing a (B) RESIDENCE: (CIT	patent. If an assign n assignment.			cument has been filed for	
Please check the appropr	riate assignee category or	categories (will not be p	rinted on the patent) :	Individual 🖵 C	orporati	on or other private gro	up entity 🖵 Government	
4a. The following fee(s)	are submitted:	4	b. Payment of Fee(s): (Ple	ease first reapply a	ny prev	viously paid issue fee s	hown above)	
Issue Fee	T 11	to D	A check is enclosed.					
☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			Payment by credit card. Form PTO-2038 is attached.  The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any					
Advance Order -	# of Copies		overpayment, to Dep	osit Account Numb	er	(enclose an	extra copy of this form).	
5. Change in Entity Sta	tus (from status indicate as SMALL ENTITY state	/	☐ b. Applicant is no lo	ngar alaiming SMA	II EN'	FITY status, See 27 CE	P 1 27(a)(2)	
							e assignee or other party in	
interest as shown by the	records of the United Sta	ites Patent and Trademark	Office.	me approxim, a reg				
Authorized Signature				Date				
Typed or printed name				Registration No.				
This collection of inform an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223	tiality is governed by 35 d application form to the ions for reducing this bu /irginia 22313-1450. DC	CFR 1.311. The informati U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain on 1.14. This collection is ear depending upon the induction office the complete process of the compl	retain a benefit by t stimated to take 12 ividual case. Any co cer, U.S. Patent and FO THIS ADDRESS	the pub minutes omment Traden S. SEN	lic which is to file (and is to complete, including is on the amount of time nark Office, U.S. Depa D TO: Commissioner for	by the USPTO to process) g gathering, preparing, and se you require to complete rtment of Commerce, P.O. or Patents, P.O. Box 1450,	

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27879	7590 02/05/2009		EXAMINER		
INDIANAPOLI	S OFFICE 27879	BOUCHELLE, LAURA A			
	GILSON & LIONE	ART UNIT	PAPER NUMBER		
ONE INDIANA S INDIANAPOLIS	SQUARE, SUITE 1600		3763		
			DATE MAILED: 02/05/2009		

## **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 436 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 436 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)				
	10/813,806	COPE ET AL.				
Notice of Allowability	Examiner	Art Unit				
	LAURA A. BOUCHELLE	3763				
The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313 1. This communication is responsive to 10/9/08.	(OR REMAINS) CLOSED in thi or other appropriate communic GHTS. This application is subj	s application. If not included ation will be mailed in due course. <b>TH</b>				
2. X The allowed claim(s) is/are 1-4,7,8,10-14,16,17 and 20-22.						
<ol> <li>Acknowledgment is made of a claim for foreign priority unally all blooms. Some claim for foreign priority unally all blooms. Some claim for foreign priority unall all blooms. None of the:         <ol> <li>All blooms claim for foreign priority unall all blooms.</li> <li>Certified copies of the priority documents have claim claim.</li> <li>Copies of the certified copies of the priority documents.</li> <li>International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* Certified copies not received:</li> </ol>	been received. been received in Application N	o	ne			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4.   A SUBSTITUTE OATH OR DECLARATION must be submit	IENT of this application.					
INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  5. CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  1) hereto or 2) to Paper No./Mail Date  (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date  Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).  6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.						
Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date  4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6.	l Date				

Application/Control Number: 10/813,806 Page 2

Art Unit: 3763

### Allowable Subject Matter

- 1. The following is an examiner's statement of reasons for allowance: The subject matter of the independent claims could not be found and was not suggested by the prior art of record. The subject matter not found is a percutaneous insertion system comprising a needle assembly, a needle hub attachment assembly comprising an elastomeric valve, an assembly comprising a hemostatic segment having a valve and an opening permitting the passage of a guidewire therethrough, in combination with the features of the invention substantially as claimed. Also not found is an percutaneous insertion system comprising a needle assembly including a first hemostatic segment, an assembly comprising a second hemostatic segment, the assembly comprising a guidewire inserter having a reverse flared tip, and the proximal end of the needle assembly is shaped to conform to the reverse flare to comprise a leak free engagement, in combination with the features of the invention substantially as claimed.
- 2. The closest prior art of record is Clinton et al (US 5295970). Clinton teaches a device for percutaneous insertion of a guidewire. Clinton fails to teach the needle hub attachment assembly having an elastomeric valve. It would not have been obvious to modify Clinton to include such a valve because as can be seen in Fig. 1 of the disclosure, the needle includes a hole 50 which make any valve added to the element useless.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle Examiner Art Unit 3763

/Laura A Bouchelle/ Examiner, Art Unit 3763

/Nicholas D Lucchesi/ Supervisory Patent Examiner, Art Unit 3763